

### **IN THE CLAIMS**

Please amend the claims to read as follows wherein changes in the claims are shown by double brackets ("[]") for deleted language and underlining ("\_\_\_") for added language.

Regular parentheses, ("()") are used, following convention, to denote named or defined quantities. Curved brackets ("{}") are used to denote mathematical groupings.

1.-131. (Cancelled)

132. (Currently Amended) A method for periodically adjusting a diabetic patient's insulin dosing therapy wherein insulin doses are to be administered as a function of Basal Insulin, Meal Insulin and Corrective Insulin, wherein Basal Insulin includes insulin doses to be administered round-the-clock, Meal Insulin includes one or more discrete doses of insulin taken in conjunction with meals which are either prescribed by dose-amount or in accordance with the formula {Meal Insulin Dose} = {amount of Carbohydrates in a meal}/CIR, where CIR is the ratio of Carbohydrate-to-Insulin, and Corrective Insulin includes one or more insulin doses taken in response to a blood glucose reading, referred to as BG, in accordance with the following formula: {Corrective Insulin Dose} = {BG – TargetBG}/CF, where CF is a Correction Factor, and TargetBG is the desired blood glucose concentration for the patient, wherein said CF, TargetBG, CIR or Meal Insulin Doses, and the rate of delivery of Basal Insulin, referred to as Basal Rate, follow schedules through a day in which their values may change in one or more scheduled time intervals during the day, wherein said therapy is adjusted by means of adjusting the schedules of CF, TargetBG, CIR or Meal Doses, and Basal Rate, wherein said adjustments are made as follows: Old Data comprised of values from a previous day or plurality of days of values of CF, CIR, Meal Insulin Doses, Basal Rates, TargetBG, Total Daily Insulin, BG's and amounts of Carbohydrates, are used to determine an output of adjusted parameters comprised of schedules for CF, CIR or Meal Insulin doses, and Basal Rates, incorporating adjusted values for said parameters for at least one time interval during the day, wherein an amount of adjustment of the sum of



Basal Insulin plus Meal Insulin during a given time interval, referred to as Prescription Insulin, is determined as a variable fraction, referred to as KrxInsl, of the Corrective Insulin for the given time interval, and wherein one of the two components of the change for Prescription Insulin either a change for adjusting Basal Insulin or a change for adjusting Meal Insulin is estimated, referred to as Preliminary Estimation, and then the other component is determined by deducting said Preliminary Estimation from the change for Prescription Insulin, wherein the Preliminary Estimation of the change for Meal Insulin for the given time interval is the change for total day's Meal Insulin multiplied times the ratio of the Old Meal Insulin determined from Old Data from a previous given time interval to a total day's Old Meal Insulin determined from Old Data from a previous day, and wherein a preliminary estimation of the change for Total Day's Meal Insulin is input by the user or estimated by a Basal-over-Total Feedback Factor (BoTFbk) multiplied times the change for Total Day's Prescription Insulin, and wherein adjustments to a patient's insulin dosing therapy are either employed in an insulin delivery device to adjust the insulin doses delivered by the device, or are outputted to a display or memory.

[[A method of adjusting an insulin dosing schedule involving a time interval of a patient's day comprising the combination of a base insulin dosage administered over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during a given time interval (Meal Insulin), and a dosage of insulin taken in response to a blood glucose test (Corrective Insulin), further involving the use of data from the time interval from one or more previous days, wherein said data includes at least one of an old Basal Insulin, an old Meal Insulin, and an old Corrective Insulin, to determine new insulin dosing parameters for future use, wherein said new parameters include one or more of a new Basal Insulin, a new Meal Insulin, and a new Carbohydrate-to-Insulin Ratio.]]

133. (Currently amended) The method of claim 132 involving the use of blood glucose test results as [[an indicator]] a quantitative measurement of error in the Basal Insulin and/or the Meal Insulin.



134. (Currently amended) The method of claim 133 wherein manually-administered blood glucose tests are used as [[an indicator]] a quantitative measurement of error in the Basal Insulin and/or Meal Insulin.

135. (Currently amended) The method of claim 133 wherein the blood glucose test results from a continuous glucose monitor are used as [[an indicator]] a quantitative measurement of error in the Basal Insulin and/or Meal Insulin.

136. (Currently Amended) The method of claim 132 wherein Corrective Insulin comprises a dose or plurality of doses of insulin, taken by the patient in response to a blood glucose test to correct the blood glucose concentration to [[its]] a prescribed target value [[(Corrective Insulin)]] ] and, is used as [[an indicator]] a quantitative measurement of error in the Basal Insulin and/or Meal Insulin.

137. (Cancel)

138. (Previously presented) The method of claim 132, wherein the given time interval constitutes a time interval amounting to less than a whole day, and there are a plurality of such intervals in the day involved.

139. (Currently amended) The method[[s]] of claim 132, wherein the [[input data (old data)]] Old Data [[used for calculating the output of new adjusted insulin treatment parameters]] is obtained from a previous day.

140. (Currently amended) The method[[s]] of claim 132 wherein the [[input data (old data)]] Old Data [[for calculating the output of new adjusted insulin treatment parameters]] is obtained from a previous plurality of days in the form of unprocessed data or condensed data [[such as averages or standard deviations]] in relation to the patient.

141. – 145. (Cancel)



146. (Currently amended) The method of claim 132, wherein the ~~[[old data are]]~~ Old Data is from a plurality of days and is obtained ~~[[downloaded into the invention program]]~~ from an insulin delivery device ~~[[pump]]~~, blood glucose meter, separately-housed microprocessor, or other point-of-care device, by means of a downloading program provided by the manufacturer of the device, ~~[[and then imported from the said downloading program into the invention program, ]]~~ wherein ~~[[said old data]]~~ the Old Data may include but are not limited to: Old Basal Rates, Old Meal Insulin, old blood glucose test results, old total daily dose of insulin, old Corrective Insulin, old amounts of carbohydrates, and/or old Carbohydrate-to-Insulin Ratio, and wherein ~~[[these old data are]]~~ the Old Data is either in chronological form or ~~[[are]]~~ is compressed for the time intervals~~[[ by totals or averages and other means]]~~.

147. (Currently Amended) The method of claim 132, wherein said ~~[[old data are downloaded directly into the invention program]]~~ Old Data is obtained from an insulin delivery device, blood glucose meter, separately-housed microprocessor, or other point-of-care device by RF, IR, visible spectrum, metal conductor, fiber optic, or sonic means ~~[[, or other means]]~~.

148. (Currently amended) The method of claim ~~[[132]]~~ 140, wherein said ~~[[old data are typed into the invention program on a keyboard]]~~ Old Data is manually entered.

149. (Currently amended) The method of claim ~~[[138]]~~ 139 wherein the boundaries for the time-intervals ~~[[boundaries]]~~ are entered by the patient as the events of the day progress.

150. – 151. (Cancel)

152. (Currently Amended) The method of claim ~~[[151]]~~ 132 wherein a change for Basal Insulin is ~~[[calculated]]~~ determined for a given time interval as the change for total Prescription Insulin for the given time interval minus the ~~[[estimated]]~~ preliminary estimate of change for Meal Insulin for the given time interval, and wherein said change for Basal Insulin is added to a previous Basal Insulin to obtain an adjusted Basal Insulin



for the given time interval, which is divided by the time duration of the given time interval to obtain an adjusted Basal Rate for the interval.

153. (Currently Amended) The method of claim 152, wherein the [[estimated]] preliminary estimate of change for the Meal Insulin for a given time interval is determined as a share of the change for total daily Meal Insulin in the same proportion as the ratio of the old Meal Insulin for the given time interval is to the total daily old Meal Insulin by the following formula: 
$$\left[ \frac{\text{The } [[estimated]] \text{ preliminary estimate of change for Meal Insulin for a given time interval}}{\left[ \frac{\text{the change in total daily Meal Insulin}}{\left[ \frac{\text{old Meal Insulin in the given time interval}}{\left[ \frac{\text{the total daily old Meal Insulin}}{\text{wherein the adjustment for total daily Meal Insulin is calculated as the adjustment for total daily Prescription Insulin multiplied by the Basal over Total Insulin Feedback factor (BoTFbk), which regulates the ratio of total daily Basal Insulin to Total Daily Dose of Insulin.}} \right]} \right]} \right] \text{ equals } \left[ \frac{\text{the change in total daily Meal Insulin}}{\left[ \frac{\text{old Meal Insulin in the given time interval}}{\left[ \frac{\text{the total daily old Meal Insulin}}{\text{wherein the adjustment for total daily Meal Insulin is calculated as the adjustment for total daily Prescription Insulin multiplied by the Basal over Total Insulin Feedback factor (BoTFbk), which regulates the ratio of total daily Basal Insulin to Total Daily Dose of Insulin.}} \right]} \right]} \right]$$

154. (Currently Amended) The method of claim ~~[[152]]~~ 153, wherein the Preliminary E[[e]]stimated adjustment [[change]] for Meal Insulin for a given time interval is determined in cases in which there is no previous record of Meal Insulin in the given time interval as 
$$\left[ \frac{\text{the } [[stem]] \text{ change for total daily Meal Insulin}}{\left[ \frac{\text{the amount of } [[old]] \text{ carbohydrates ingested during the given time interval for one or more previous time intervals}}{\left[ \frac{\text{the total daily amount of } [[old]] \text{ carbohydrates for one or more previous days}}{\right]} \right]} \right]$$

155. (Cancel)

156. (Currently Amended) The method of claim ~~[[155]]~~ 132 ~~[[of determining]]~~ further comprising obtaining a change for Meal Insulin in a given time interval by adopting the preliminary estimate of the change for Meal Insulin [[as (the change for Prescription Insulin for the given time interval) minus (the change for the Basal Insulin for the given time interval)]].



157. (Currently amended) The method of claim [[156]] 132 wherein the change for adjusting Meal Insulin is calculated as [[of calculating new Meal Insulin for a given time interval as ( the old]] a Meal Insulin from one or more previous time intervals [[from a previous day or plurality of days]] plus the adjustment for Meal Insulin for the given time interval, wherein said adjustment is calculated as [[(]]{the change in Prescription Insulin for the given time interval}{(]}] minus [[(]]{the [[estimated]] Preliminary Estimation of change [[in]] for adjusting Basal Insulin}{(]}] wherein the Preliminary Estimation of the change for adjusting Basal Insulin is determined as {adjusted Basal Rate minus a Basal Rate from one or more previous time intervals} multiplied times the duration of the time interval, or wherein the said adjustment for Meal Insulin is an estimated adjustment, and further including determining a Carbohydrate-to-Insulin Ratio by dividing the amount of carbohydrates ingested during one or more previous given time intervals by the adjusted Meal Insulin for the given time interval.

158. – 159. (Cancel)

160. (Currently amended) The method of claim 158 wherein [[the]] an adjusted [[new]] Basal Rate is displayed, and a user either accepts the adjusted Basal Rate or inputs a further-adjusted value for the Basal Rate [[by the practitioner]] after viewing the adjusted Basal Rate displayed [[a recommendation calculated for a given time interval as the change for total Prescription Insulin for the given time interval minus the estimated change for Meal Insulin for the given time interval]].

161. – 162. (Cancel)

163. (Currently amended) The method of claim [[144]] 132, wherein [[a new]] an adjusted Carbohydrate-to-Insulin Ratio is calculated for [[the]] a whole day as [[(]]{total daily amount of carbohydrates) divided by [[(]]{total daily [[old]] Meal Insulin for a previous day}{(]}] plus [[(]]{the change for total daily Prescription Insulin}{(]}] minus [[(]]{the change for total daily Basal Insulin}{(]}].

164. – 167. (Cancel)



168. (Currently amended) The method of claim [[166]] 132 wherein [[a new]] an adjusted value for a given parameter is calculated using [[old]] data from a different interval on a previous day or plurality of days.

169. (Currently amended) The method of claim [[166]] 132, wherein [[a new]] an adjusted value for a given parameter is obtained for the given interval by applying an [[adjustment]] Interval-Equivalence [[f]]Factor to the value of said parameter from a different time interval.

170. (Currently amended) The method of claim 169, wherein, for a parameter whose source is a different time interval on the same day, the said [[adjustment]] Interval-Equivalence [[f]]Factor is determined as a ratio of;  $\frac{[[()]\{\text{the value of the said parameter from the given time interval on a previous day or plurality of days}\}()]}{[[()]\{\text{the value of the said parameter from the different time interval on the previous day or plurality of days}\}()]}$ .

171. (Currently amended) The method of claim 169, wherein the [[adjustment]] Interval-Equivalence [[f]]Factor is determined from a statistical correlation from the patient's old data.

172. (Currently amended) The method of claim 169, wherein the [[adjustment]] Interval-Equivalence [[f]]Factor is determined from a statistical correlation taken from a sampling of a plurality of patients.

173. (Currently amended) The method of Claim 152 wherein [[an]] a preliminary estimated change for adjusting in the Meal Insulin for a given time interval is calculated as:  $\frac{[[()]\{\text{the [[new]] adjusted Meal Insulin in the given time interval}\}()] - [[()]\{\text{the [[old]] Meal Insulin in the given time interval for one or more previous days}\}()] }{ \text{wherein the adjusted Meal Insulin for a given time interval is determined as } \{ \text{the amount of [[old]] carbohydrates in the given time interval for one or more previous days} \} \text{ divided by } \{ \text{the adjusted Carbohydrate-to-Insulin Ratio for the given time interval} \} }$ .



174. – 175. (Cancel)

176. (Currently amended) The method of claim [[162 or]] 173, wherein the adjusted [[estimated change in the Meal Insulin is determined from the formula: (amount of old carbohydrates ingested during current time interval)/(new]] Carbohydrate-to-Insulin Ratio is displayed and a user either accepts the adjusted Carbohydrate-to-Insulin Ratio or inputs a further-adjusted value for the Carbohydrate-to-Insulin Ratio. [[for the given time interval) minus (old Meal Insulin for the given time interval).]]

177. (Currently amended) The method of claim 132 wherein the method [[invention]] is embodied in the form of a digital program installed in a microprocessor in a small portable device suitable for individual patients to use several times per day[[.]] , the small portable device being selected from the group consisting of a palm-sized computer, a blood glucose meter or other blood-glucose measuring device, or an insulin delivery device.

178. (Currently amended) The method of claim 132 wherein the adjusted Correction Factor (CF) is calculated as a constant multiplied times the adjusted CIR and divided by Body Weight. [[The method of claim 177 wherein the invention is embodied in the form of a digital program installed in a palm-sized computer, a blood glucose meter or other blood-glucose measuring device, an insulin pump, an insulin pen, an insulin inhaler, or other insulin delivery device.]]

179. (Currently amended) The method of claim 132 wherein the Correction Factor (CF) is calculated as a constant multiplied times the adjusted CIR. [[The method of claim 177 wherein the invention is embodied in the form of a digital program installed in an insulin pump or blood glucose meter used with an insulin pump.]]

180. (Previously presented) The method of claim 177 wherein [[the]] data from one or more previous days [[day's data]] is stored in the device[[used as the old data in the calculations]].



181. – 182. (Cancel)

183. (Currently Amended) The method of claim ~~[[182]]~~ 132 wherein the method ~~[[invention]]~~ is embodied in the form of a digital program installed in a personal ~~[[laptop]]~~ computer or mainframe used by the medical workers, and wherein the data from a plurality of previous days is stored therein, and including an on-screen display for displaying adjusted Basal Rates for a practitioner to review and manually adjust, and a re-calculation of a Meal Insulin or a CIR schedule, using the manually adjusted Basal Rates as input.

184. – 187. (Cancel)

188. (Currently Amended) The method of claim ~~[[187]]~~ 132 for use with insulin of the long-acting chemical type which requires very few shots per day ~~[[whereby]]~~ wherein the rate of administration of Basal Insulin is a constant value for ~~[[the]]~~ a whole day and is equal to the total daily Basal Insulin divided by the time in the day, which may be up to 24 hours.

189. (Currently Amended) The method of claim ~~[[141]]~~ 132, wherein a change for Prescription Insulin for a given time interval is a number that has an absolute value less than that of ~~[[the old]]~~ a Corrective Insulin dosage for ~~[[the]]~~ a previous time interval and has the same sign~~[[.]]~~, and the change for Prescription Insulin for the given time interval is determined for the given time interval as: the multiplying factor, referred to as KrxInsl, times the Corrective Insulin for a previous time interval at the end of the time interval, wherein the multiplying factor KrxInsl is a number between zero and one, chosen or calculated to provide a means of causing the value for Corrective Insulin to converge over successive dosing cycles ultimately to near-zero in all the time intervals, wherein the multiplying factor KrxInsl is optimized to provide the smallest number of cycles to approach convergence within the limitations of the patient's safety.

190. (Cancel)



191. (Currently amended) The method of claim ~~[[189]] 132~~ wherein the ~~[[stem]]~~ change ~~for~~ ~~[[in the]]~~ a total daily Prescription Insulin is manually input.

192. – 194. (Cancel)

195. (Currently amended) The method of claim ~~[[193]] 189~~ wherein ~~[[the old]]~~ data for a previous time interval is from a plurality of days, and the multiplying factor KrsInsl is manually input by the practitioner~~[[ during a pause in the interactive program]]~~.

196. (Currently amended) The method of claim ~~[[192]] 189~~, wherein the multiplying factor KrxInsl is calculated as: ~~[[{the change in total daily Prescription Insulin}]]~~ divided by ~~[[{the total daily [[old]] Corrective Insulin for a previous day}]]~~, and once calculated, ~~[[it may be]]~~ used in some or all of the plurality of time intervals comprising the day.

197. (Currently amended) The method of claim ~~[[193]] 189~~, wherein the multiplying factor KrxInsl is determined as follows: the following two parameters: a small fraction, referred to as Epsilon, to signify a fraction left after convergence, and the Number of Cycles to Convergence (N) are set by a user, then the multiplying factor KrxInsl is calculated as {One minus Epsilon} [(a small fraction representing the near-zero percent of an original total daily Corrective Insulin allowed to remain at the end of a given response time)] raised to the power [(one divided by N)] [the number of adjustment cycles, days, or office-visits in which it is desired to reduce the total daily Corrective Insulin to near-zero), and wherein the small near-zero fraction and the number of adjustment cycles are pre-set or input by the practitioner].

198. (Currently amended) The method of claim ~~[[142]] 132~~ wherein ~~[[the]]~~ a change for the total daily Meal Insulin is manually input.

199. (Currently amended) The method of claim ~~[[142]] 132~~ wherein ~~[[the]]~~ a change ~~[[in]]~~ for the total daily Basal Insulin is manually input.



200. (Currently amended) The method of claim [[201]] 132, wherein [[a]] the feedback factor, referred to as BoTFbk, [[mechanism]] is used in all time intervals to regulate the relative proportions of Basal Insulin and Meal Insulin as parts of the Prescription Insulin by the formula: {change for Basal Insulin} = BoTFbk multiplied times {change for Prescription Insulin}, or by the formula: {change for Meal Insulin} equals {1 – BoTFbk} multiplied times {change for Prescription Insulin}.

201. (Cancel)

202. (Currently amended) The method of Claim [[201]] 132 wherein [[Basal Insulin is in the master role and the stem]] a change for [[in]] total daily Basal Insulin is determined by finding the minimum of the absolute values of the following two quantities: [[({change in total daily Prescription Insulin})]] and [[({a target total daily Basal Insulin minus [[the old]] a total daily Basal Insulin for a previous day)}]], then affixing the sign of the latter quantity, and wherein this result is divided by the change for Prescription Insulin for a total daily period to obtain an adjusted value of the feedback factor BoTFbk.[[and wherein the roles of Basal Insulin and Meal Insulin may be reversed by simple substitution of one for the other]]

203. (Cancel)

204. (Currently amended) The method of claim [[203]] 132, wherein the feedback factor BoTFbk is calculated as follows: If the adjustment[[change]] for total daily Prescription Insulin is zero or positive then the feedback factor BoTFbk is the [[quantity: (the current ratio of Basal Insulin to total daily dose of insulin) minus (a constant whose value is from zero through 1) multiplied by (the said current ratio of Basal Insulin to total daily dose of insulin minus a)] desired target value for said ratio, referred to as BoTTgt, or if the adjustment [[change]] for total daily Prescription Insulin is negative then the feedback factor BoTFbk is {one minus [[the]] BoTTgt}[[said quantity]].

205. – 206. (Cancel)



207. (Currently amended) The method of Claim 204, wherein a target ratio of  $\frac{\text{total daily Meal Insulin}}{\text{total daily dose of insulin}}$  is calculated for the given time interval as one minus the target ratio of  $\frac{\text{total daily Basal Insulin}}{\text{total daily dose of insulin}}$ .

208. (Currently amended) The method of claim 200, wherein the roles of Meal Insulin and Basal Insulin are reversed [is given the master role in the calculations of claim 202 and all claims dependent to said claim]] by means of a simple mathematical exchange of the two terms Basal Insulin and Meal Insulin throughout.

209. (Currently Amended) The method of Claim ~~[[208]]~~ 200 wherein a target ratio of  $\frac{\text{Basal [Meal] Insulin}}{\text{total daily dose}}$  Total Daily Dose of insulin  $\frac{\text{Basal [Meal] Insulin}}{\text{total daily dose}}$  is determined as the quantity of  $\frac{1 - \{\text{total amount of carbohydrates ingested over a day}\}}{\{\text{an Average Glycemic Index}\}}$  divided by  $\frac{\{\text{the result of a statistically based formula for daily energy requirements of a patient, given the patient's body measurements or other parameters}\}}{\{\text{the result of a statistically based formula for daily energy requirements of a patient, given the patient's body measurements or other parameters}\}}$ , provided that the units of the numerator and denominator are the same.

210. (Currently amended) The method of Claim ~~[[202]]~~ 200 wherein [the] a target ratio of Basal Insulin divided by Total Daily Dose of insulin is set for the patient by the practitioner and manually input. [[ estimated stem change for total daily Meal Insulin is multiplied by a fractional reduction factor if the change is in the positive direction]]

211. – 212. (Cancel)

213. (Currently amended) The method of claim 132 ~~[[211 of]]~~ including calculating a change for Carbohydrate-to-Insulin Ratio CIR for a given time interval for early-model insulin pumps, in a way that does not require historical data of the amount of carbohydrates, by multiplying an adjustment ~~[[change]]~~ for Meal Insulin by the rate of change of Carbohydrate-to-Insulin Ratio CIR with respect to Meal Insulin as determined by a calculus derivative of a population-based correlation ~~[[of Carbohydrate to Insulin Ratio with respect to Meal Insulin]]~~.



214. (Currently amended) The method of claim 213, including calculating said derivative using the calculus chain rule as the derivative of Carbohydrate-to-Insulin Ratio CIR with respect to Total Daily Dose of insulin times the derivative of Total Daily Dose of insulin with respect to Meal Insulin, where Carbohydrate-to-Insulin Ratio CIR as a function of Total Daily Dose of insulin and Total Daily Dose of insulin as a function of Meal Insulin are both population-based statistical correlations [[the negative of the grams of carbohydrates ingested during a given time interval divided by the square of the Meal Insulin]].

215. - 216. (Cancel)

217. (Currently amended) The method of claim ~~[[216]]~~ 214, wherein the population-based correlation of Total Daily Dose of insulin, referred to as TDD, as a function of Meal Insulin is the formula:  $TDD = \{Meal\ Insulin\}$  multiplied times  $\{a\ constant\ less\ than\ one\}$  [[including estimating the old Meal Insulin as a fraction of the total daily dose of insulin]].

218. (Currently amended) The method of claim 217, wherein the constant ~~[[fraction]]~~ is pre-set to one-half.

219. (Cancel)

220. (Currently amended) The method of claim ~~[[219]]~~ 214, wherein the statistical correlation estimates Carbohydrate-to-Insulin Ratio CIR as given by a correlation constant times body weight divided by ~~[[old]]~~ total daily dose of insulin for a previous day.

221. (Currently amended) The method of claim ~~[[219]]~~ 214, wherein the statistical correlation estimates Carbohydrate-to-Insulin Ratio CIR as given by a correlation constant divided by ~~[[old]]~~ total daily dose of insulin for a previous day.



222. (Currently amended) The method of claim ~~[[219]]~~ 214, wherein the statistical correlation estimates Carbohydrate-to-Insulin Ratio CIR as given by a correlation constant divided by body weight.

223. (Currently amended) The method of claim ~~[[219]]~~ 220, wherein correlation constant is 2.8~~[[the statistical correlation estimates Carbohydrate-to-Insulin Ratio CIR as a correlation constant times body weight divided by the quantity of (total daily dose of insulin multiplied by height cubed)]]~~.

224. (Currently amended) The method of Claim ~~[[138]]~~ 132 further including the method of correcting for old data containing one or more missing or unusable consecutive blood glucose tests or Corrective Insulin dosages for a given previous time interval by assigning a value of zero to the Corrective Insulin for the given previous time interval or assigning the value of TargetBG to the value of a previous blood glucose reading BG~~[[considering the elapsed time since the last blood glucose test actually performed as one large time interval ending at the time interval boundary associated with the next old blood glucose test actually performed, and applying the results of the calculations relating to said large time interval to each of the consecutive component intervals]]~~.

225. – 226. (Cancel)

227. (Previously presented) The method of claim 132, wherein the sum of ~~[[old]]~~ a Meal Insulin for a previous given time interval and an ~~[[old]]~~ After-Meal Corrective Insulin dosage for a previous given time interval is used in place of Meal Insulin.

228. (Currently amended) The method of claim 132 wherein the given time interval is divided into two sub-intervals, the earlier~~[[first]]~~ of which starts near the end of a meal and runs to the approximate time of an after-meal Corrective Insulin dosage in the interior of the given time interval, and the later sub-interval of the given time interval starts at the approximate time of the after-meal Corrective Insulin dosage and runs to the end of the given time interval at the next regular (pre-meal) Corrective Insulin dosage,



and in which a change to the Basal Rate is determined based on the later time sub-interval and is applied over the whole given time interval, including the earlier sub-interval, in which it is used to calculate a change for Meal Insulin, and wherein the parameter KrxInsl has two different values in the two subintervals, namely KrxInslEarlier and KrxInslLater, wherein these two parameters may be equal or may have any value from zero through one, including the value of KrxInsl for a whole day.

229. (Currently amended) The method of Claim 132 wherein [[the given time interval is divided into two sub-intervals: an earlier sub-interval and a later sub-interval that starts at the approximate time of an after-meal Correction Insulin dose in the interior of the main given time interval.]] pre-meal BG's and pre-meal Corrective Insulin doses are identified by their time-proximity to the Meal Insulin dose for a meal or other occurrence, and after-meal BGs and after-meal Corrective Insulin doses are identified by their time-occurrence in an after-meal time window, which starts at a delay-time after the Meal Insulin dose and ends after a duration, wherein the delay-time and duration are set by the user, wherein the Meal Insulin dose-time used as the time reference is the time of the first Meal Insulin dose in the interval or the average time of the Meal Insulin doses in the interval.

230. (Currently amended) The method of claim [[229]] 228, of calculating the Basal Rate in the later sub-interval in the manner wherein a change for Basal Insulin is calculated for a given time interval as the change for Prescription Insulin for the given time interval minus the [[estimated]] preliminary estimate of change for Meal Insulin for the given time interval, wherein the following parameters may be different in the later sub-interval from the earlier sub-interval and may be also be different from other intervals: the target for blood glucose concentration, and the following unit-less ratios, each with a range of zero through one: target ratio of total daily Basal to Total Daily Dose of insulin; [[target ratio of total daily Meal Insulin to Total Daily Dose;]] BoTFbk, and [[Multiplying factor]] KrxInsl.

231. (Currently amended) The method of claim [[229]] 228 of calculating [[the]] Meal Insulin in the earlier sub-interval[[in the manner of claim 158]], using [[the old]] a previous after-meal Corrective Insulin value in the calculations wherever [[old]]



Corrective Insulin is called-for, wherein the following parameters may be different in the later sub-interval from the earlier sub-interval and may be also be different from other intervals: the target for blood glucose concentration, and the following unit-less ratios, each with a range of zero through one: target ratio of total daily Basal to Total Daily Dose of insulin; [[target ratio of total daily Meal Insulin to Total Daily Dose; feedback factor for Basal, feedback factor for Meal Insulin]] BoTFBk, and [[Multiplying factor]] KrxInsI.

232. (Currently amended) The method of claim [[229]] 228, wherein the change for the Prescription Insulin in the later portion of the time interval is a multiplying factor [[(I)] KrxInsILater(I)] times [[the old]] a previous Corrective Insulin dosage at the end of the time interval.

233. (Currently amended) The method of claim [[229]] 228, including dividing the change for the Basal Insulin for the later sub-interval by the elapsed time over the later sub-interval to obtain a change in Basal Rate, then adding this change to the previous Basal Rate for the entire given time interval to obtain [[a new]] an adjusted Basal Rate for the entire given time interval.

234. (Currently amended) The method of claim [[231]] 228, wherein the change in the Prescription Insulin for the earlier time sub-interval is calculated as [[a]] the multiplying factor [[(I)] KrxInsIEarlier(I)] times [[the old]] a previous After-Meal Corrective Insulin dosage in the interior of the main given time interval.

235. (Currently amended) The method of claim [[229]] 228, wherein the multiplying factor KrxInsIEarlier used in the Meal Insulin calculation in the earlier sub-interval is a constant times the multiplying factor KrxInsILater used in the Basal Insulin calculation in the later sub-interval [[i.e.  $KrxInsIEarlier = \text{constant} * KrxInsILater$ ]], and wherein the constant may have any value from zero through one, inclusive of the endpoints.



236. (Currently amended) The method of claim [[229]] 228, wherein the multiplying factor used for determining the change in the Prescription Insulin in the earlier sub-interval  $KrxInsI_{Earlier}$  is a constant times the multiplying factor  $KrxInsI$  for the whole day [[described in claim 192]] and the multiplying factor used for determining the change in the Prescription Insulin in the later sub-interval  $KrxInsI_{Later}$  is a different constant times  $KrxInsI$ , and wherein the constants may be equal and may have any value, including one and zero.

237. (Currently amended) The method of claim 189, wherein the change to Prescription Insulin is adjusted [[based on]] as a function of a percent standard deviation of a patient's blood glucose tests [[in]] over a plurality of previous days [[a recent calendar period]] compared to the mean percent standard deviation of a population sample, and wherein if the patient's standard deviation is higher than the mean standard deviation of the population sample, then less change in the Prescription Insulin is allowed, and wherein this is accomplished by means of a multiplying factor  $F_{InsAuto}$  that changes from one to zero as the percent standard deviation of a patient's BG's increases[[employed than the change determined]].

238. (Currently amended.) The method of claim [[189]] 237, wherein the multiplying factor  $F_{InsAuto}$  decreases linearly from one to zero as the ratio of {patient's percent standard deviation of BG's} / {population percent standard deviation of BG's} increases[[stem change for total daily Prescription Insulin is limited to a maximum change value based on a set fraction of the total daily Corrective Insulin]].

239. (Cancel)

240. (Currently amended) The method of claim [[239]] 237, wherein the multiplier  $F_{InsAuto}$  is determined as follows: if {the patient's percent standard deviation of blood glucose measurements} is less than  $\{ \{ \{ \{ \text{the mean of the population percent standard deviations} \} \text{ plus } \{ \text{the } [[one]] \text{ standard deviation of } \{ \text{the population percent standard deviations} \} \} \} \}$ , then the value of the multiplier  $F_{InsAuto}$  is one (1); if {the patient's percent standard deviation of blood glucose measurements} is  $[[a factor]]$



between one and two times the percent standard deviations of the population standard deviation greater than the mean of the population percent standard deviation, then the multiplier  $F_{InsAuto}$  ramps linearly downwardly until it reaches zero at the upper bound of this interval; and if the patient's standard deviation of blood glucose measurements is greater than this, then the multiplier  $F_{InsAuto}$  is zero, allowing no change in Prescription Insulin.

241. (Currently amended) A method for adjusting a diabetic patient's insulin dosing parameters within an insulin delivery device or within a practitioner's computer, wherein the diabetic patient receives insulin doses as a function of Basal Insulin, Meal Insulin and Corrective Insulin, wherein Basal Insulin includes insulin doses administered round-the-clock and which may be administered in a long-acting form or a short-acting form from the delivery device in which the rate of administration of Basal Insulin, referred to as Basal Rate, may be scheduled, wherein Meal Insulin includes one or more discrete doses of insulin taken in conjunction with meals either pre-prescribed or in accordance with the formula {Meal Insulin Dose} = {amount of Carbohydrates in a meal}/CIR, where CIR is the ratio of Carbohydrate-to-Insulin, wherein Corrective Insulin includes one or more doses of insulin taken in response to a blood glucose reading, referred to as BG, in accordance with the following formula: {Corrective Insulin Dose} = {BG – TargetBG}/CF, where CF is a Correction Factor, and TargetBG is the desired blood glucose concentration for the patient, and wherein the patient's day is divided into one or more time intervals, wherein data, referred to as Old Data, is comprised of values from a previous day or plurality of days of values of CF, CIR, Basal Rates, Meal Insulin Doses, TargetBG, Total Daily Insulin, BG's and amounts of Carbohydrates, are used as input for determining an output of adjusted parameters comprised of schedules for CF, Basal Rate, Meal Insulin and CIR, incorporating a value of each parameter for each time interval during the day, wherein said method comprises adjusting the parameters, wherein the adjustment for Meal Insulin for a given time interval is estimated by the following formula: {adjustment for Meal Insulin for the given time interval} = {total daily Corrective Insulin for previous day \*  $K_{RxInsI}$ } \* {Meal Insulin for a previous given time interval} / {total daily Meal Insulin for a previous day} \* {1-  $B_{OTFbk}$ }, where  $K_{RxInsI}$  is a variable fraction from zero through one that determines the size of all the adjustments



and is set for a balance between speed of convergence and patient safety, and wherein BoTFbk is a feedback factor whose purpose is to bring the patient's ratio of Basal Insulin/Total Insulin to a target value, and wherein the adjustment for Basal Rate is given by the formula: {adjustment for Basal Rate in the given time interval} = {{total previous Corrective Insulin value \* KrxInsl } – {adjustment for Meal Insulin for the interval }} / {time duration of the interval}, and wherein the adjusted CIR in a given time interval is calculated as the amount of Carbohydrates in a previous given interval divided by the adjusted Meal Insulin and wherein said adjustments are employed in the insulin delivery device to adjust the insulin doses delivered by the device or are outputted to a display or memory[[A method of adjusting an insulin dosing schedule involving a time interval of a patient's day comprising the combination of a base insulin dosage administered over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during the given time interval (Meal Insulin), and involving a dose of insulin determined from a blood glucose test result (Corrective Insulin) as an indicator of error in the Basal Insulin and/or the Meal Insulin and further involving the use of data, known as old data, from the given time interval from one or more previous days, including at least one of an old Basal Insulin, an old Meal Insulin, and an old Corrective Insulin, to determine new insulin dosing parameters for future use, wherein said new parameters may include one or more of a new Basal Insulin, a new Meal Insulin, and a new Carbohydrate-to-Insulin Ratio]].

242. (Cancel)

243. (Currently amended) The method of claim[[s]] 132 [[140]], wherein the following formula is used: [[(]]{a new} an adjusted Carbohydrate-to-Insulin Ratio for a given time interval{[[]]} equals [[(old)]{amount of carbohydrate in the previous given time interval{[[]]} divided by [[(old)]{Meal Insulin in the previous given time interval{[[]]} plus [[(]]{the [[stem]] change for [[total daily]] Total Daily Prescription Insulin{[[]]} multiplied by [[(old)]{Corrective Insulin in the previous given time interval{[[]]} divided by [[(]]{total daily [[old]] Corrective Insulin in the previous given time interval{[[]]} minus [[(]]{[[new]] adjusted Basal Rate in the given time interval{[[]]} minus [[old]]{Basal Rate in the previous given time interval{[[]]} times [[(]]{duration of the given time interval{[[]]}].



244 (Cancel)

245. (Currently amended) The method of claim 139, wherein the adjusted Basal Rate for the given time interval is:  $\{[[Old]] \text{ Basal Rate for the } \underline{\text{previous}} \text{ given time interval}\} + \{K_{rx} \text{ Insulin divided by the duration of the given time interval}\} * \{[[old]] \text{ Corrective Insulin in the } \underline{\text{previous}} \text{ given time interval}\} \text{ minus } \{1 - BoT_{FBk}\} * \{\text{total daily } [[old]] \text{ Corrective Insulin for a previous day}\} * \{[[old]] \text{ Meal Insulin in the } \underline{\text{previous}} \text{ given time interval}\} \text{ divided by } \{\text{total daily } [[old]] \text{ Meal Insulin for a previous day}\}$ .

246. (Currently amended) The method of claim 139, wherein the adjusted Carbohydrate-to-Insulin Ratio CIR for a given time interval is:  $\{[[old]] \text{ amount of carbohydrates in the } \underline{\text{previous}} \text{ given time interval}\} \text{ divided by } \{[[old]] \text{ Meal Insulin in the } \underline{\text{previous}} \text{ given time interval}\} + K_{rx} \text{ Insulin} * \{[[old]] \text{ Correction Insulin in the } \underline{\text{previous}} \text{ given time interval}\} \text{ minus } \{\{\text{adjusted Basal Rate for the given time interval}\} \text{ minus } \{[[old]] \text{ Basal Rate in the } \underline{\text{previous}} \text{ given time interval}\}\} * \{\text{the duration of the given time interval}\}$ .

247. – 259. (Cancel)

260. (Currently amended) The method of claim ~~1189~~ 132 wherein ~~the~~ a practitioner's input of a change for total daily Prescription Insulin is locked-out if ~~it~~ the change causes the quantity of total daily ~~old~~ Corrective Insulin for a previous day divided by the change in the total daily Prescription Insulin to be less than one.

261. – 267. (Cancel)

268. (Currently amended) The method of claim 150 wherein the ~~denominator of the Corrective Insulin formula~~ Correction Factor CF is determined in intervals that are divided into two sub-intervals by an After-Meal Corrective dose of insulin as follows:  $\{\text{New } \underline{\text{Adjusted}} \text{ Correction Factor}\} \text{ equals } \{\text{Old Correction Factor}\} \text{ plus } k_1 \text{ multiplied by } \{[[[]]] \{ \{ \{ \text{After-Meal Blood Glucose test result} \} \} \} \text{ minus } [[[]] \{ \text{target value for after-meal blood glucose} \} \} \} \text{ divided by } [[[]] \{ k_2 \text{ times } [[[]] \{ \text{After-Meal Blood Glucose test result} \} \} \} \text{ plus } (\text{end-of interval Blood Glucose test result} \} \} \} \text{ minus two times } [[[]] \{ \text{target}$



value for After-Meal Blood Glucose}}{[()]}} minus  $k_3$  times Old Correction Factor}}{[()]}}

where  $k_1$ ,  $k_2$ , and  $k_3$  are constants that may have any value including one and zero.

269. (New) The method of claim 241, wherein the following formula is used: {an adjusted Carbohydrate-to-Insulin Ratio for a given time interval} equals {amount of carbohydrate in the previous given time interval} divided by {{Meal Insulin in the previous given time interval} plus {the change for Total Daily Prescription Insulin} multiplied by {Corrective Insulin in the previous given time interval} divided by {total daily Corrective Insulin in the previous given time interval} minus {{adjusted Basal Rate in the given time interval} minus {Basal Rate in the previous given time interval}} times {duration of the given time interval}}.